REMARKS

Claims 1-55 are pending in the application and subject to a Restriction Requirement. Consistent with the response to the Restriction Requirement provided below, Applicants herein cancel claims 9-13, 21-52, 54 and 55 without prejudice or disclaimer, withdraw claims 19 and 20, and add new claims 56-58, (dependent from claim 1). Claims 1-8, 14-18, and withdrawn claims 19-20, are amended herein to remove non-elected subject matter (subject to an election without traverse), to correct dependency, and to simplify wording and enhance readability of the claims. No new matter is added by way of the amendments or new claims.

In the Office Action dated October 4, 2008, the Examiner requires restriction under 35 U.S.C. §121 and 372 to one of the following groups.

Group I.	Claims 1-10, 14 (only as it pertains to bleb) and 16-18, drawn to a Neisserial bleb preparation.
Group II.	Claim 11, drawn to a Neisserial bacterial strain.
Group III.	Claims 12, 13, 14 (only as it pertains to LOS), 15 and 16-18 and 53, drawn to a LOS preparation.
Group IV.	Claims 19 and 20, drawn to a method of manufacturing a Neisserial bleb preparation.
Group V.	Claims 21-39, and 55, drawn to a bleb preparation from any Gram-negative bacterial strain comprising an outer-membrane protein conjugated to LOS integrated in the outer membrane.
Group VI.	Claims 40-52, and 54, drawn to a process of producing an intra-bleb conjugated bleb preparation from a Gram-negative bacterial strain comprising an outer membrane protein conjugated to LOS integrated into the outer membrane.

Applicants elect Group I, species b) directed to Neisserial bleb preparations derived from an lgtB$^-$ neisserial strain with an L3 LOS immunotype without traverse

Although Applicants disagree with the Examiner's allegation that the claims lack unity of invention under PCT Rules 13.1 and 13.2 (as will be discussed below), to facilitate prosecution, Applicants elect Group I without traverse. In Group I, the Examiner further requires election of a single species of bleb preparations selected from blebs:

a) derived from a strain with a neisserial L2 LOS immunotype and a lgtB$^-$ strain;

b) derived from a strain with a neisserial L3 LOS immunotype and a lgtB$^-$ strain; and

c) a combination of blebs derived from a neisserial strain with an L2 LOS immunotype and a neisserial strain with an L3 LOS immunotype.

Applicants elect the species of b) without traverse (*i.e.*, blebs derived from an lgtB- strain with an L3 LOS immunotype). However, Applicants note that the subject matter of claims 9 and 10 is not consistent with the election of Group I b), because claims 9 and 10 include neither the limitation that the strain from which the blebs are prepared is of the L3 immunotype, nor that the strain is an lgtB$^-$ strain. Accordingly, Applicants respectfully request that claims 9 and 10 be placed in a separate group (Group VII) for purpose of examination on the merits. To facilitate prosecution, Applicants have cancelled claims 9 and 10. In the event that the Examiner prefers not to revise the Restriction Requirement as suggested, Applicants will resubmit claims directed to the subject matter of cancelled claims 9 and 10.

Applicants traverse the requirement that the invention be restricted to a single species of downregulated capsular polysaccharide gene.

The Examiner indicates that Applicants must also elect a downregulated capsular polysaccharide gene, and indicates that this requirement is NOT a species election. To the extent that the Examiner maintains this requirement with respect to the amended claims of Group I, Applicants provisionally elect siaD with traverse. Applicants note that, contrary to the indication on page 2 of the Office Action that claims 4-10 are directed to downregulated capsular polysaccharide genes, claims 5-8 include further limitation to dowregulated lipid A genes, outer membrane protein genes, combinations of outer membrane protein genes and outer membrane protein antigens, respectively.

As a preliminary matter, Applicants would have no disagreement with requirement to elect a single species of downregulated capsular polysaccharide gene for purpose of initial examination (*i.e.*, siaD), with the understanding that in the event that one or more generic claims (*e.g.*, claims 1-3) are found allowable, that additional species, which are dependent from or otherwise include all of the limitations of the allowed generic claim, will be examined as required under 37 CFR § 1.141.

However, to the extent that the Examiner maintains a requirement for restriction to a neisserial bleb preparation derived from an lgtB$^-$ strain with an L3 LOS immunotype that is exclusively downregulated for a single capsular polysaccharide gene (*e.g.*, siaD), and requires

cancellation of the remaining subject matter, Applicants traverse because such a requirement precludes allowance of the full scope of the generic invention.

Alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. Such a *de facto* rejection of the claims does not conform to the 35 U.S.C. §121, as expressly articulated by the C.C.P.A.

As the C.C.P.A. noted (emphasis added):

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *See, In Re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

An Examiner may not reject a particular claim on the basis that it represents independent and distinct inventions (*e.g.*, because the "preparations are structurally different and possess different immunogenic properties). *See, In Re Weber, Soder and Boksay, Supra.* The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I* and *In Re Haas II.* In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. For example, *In re Weber* (198 USPQ 328) sets forth the following (*see*, 331-332):

> It is apparent that §121 provides the commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a

> basis for an examiner, acting under the authority of the commissioner to reject a particular claim on the same basis.

In re Haas (198 USPQ 335) interprets this as a *per se* holding, in the very next case by the court:

> In *In re Weber...*, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed as a basis for rejection, that rejection is, on the authority of Weber, reversed.

As the Court has also noted:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.
> *See, In Re Weber, Soder and Boksay* at 334.

Instead of improperly imposing a restriction requirement on a single claim, the Office may limit initial examination to a reasonable number of species encompassed by the claim. *See,* 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative considerations and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are complied with. *See,* the MPEP at 803.02. *See also, In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are simply incapable of capturing the full scope of the invention.

In view of the case law cited above, Applicants respectfully submit that the Office is simply forbidden from restricting a single claim (*e.g.*, claim 4) into multiple groups, because 1) such a restriction is necessarily a rejection of the claim (i.e., there is no application where an applicant is permitted to pursue the claim as drafted); and 2) the court has explicitly held that §121 does not provide a basis for such a rejection (and the court has, quite bluntly and unequivocally, held that this is a per se holding). Because the restriction is improper, Applicants respectfully request that the different species of downregulated capsular polysaccharide gene be rejoined subject to a requirement for election of species for initial examination as described above. Furthermore, should the Examiner believe that additional

elections of species (*e.g.*, in claims 5-8) are warranted, the Examiner is invited to telephone Applicants undersigned attorney for a telephonic election.

Applicants reserve the right to petition and/or appeal the Restriction Requirement

Applicants note that the courts have explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. *See, In Re Haas I, supra.* Because restriction of a single claim into multiple groups is a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, Applicants expressly reserve the right to appeal any decision that may be made regarding the present Restriction Requirement to the Patent Office Board of Appeals and to the Federal Circuit, in this or any future related application.

Applicants request rejoinder of allowable product and process claims as required by MPEP §831.04(b).

Applicants also note that the subject matter of Groups I and IV are related to each other as product and process of making the product. When product claims (for example, one or more of claims 16-18) are found to be allowable, Applicants respectfully request rejoinder of process claims (19 and 20) that are dependent or otherwise include all of the limitations of the allowed product claims as required by MPEP §831.04(b).

Quakyi does not destroy novelty of the claimed invention

The Office Action predicates the above restriction on the allegation that the disclosure of Quakyi *et al.* (Infection and Immunity 65, no. 5, pages 1972-1979, 1979) destroys novelty of the claims of Group I. Applicants respectfully disagree. The invention of claim 1 is a "Neisserial bleb preparation derived from an lgtB$^-$ neisserial strain with an L3 LOS immunotype." All of the preparations described by Quakyi *et al.*, are from strains M986, a non-capsular variant thereof designated NCV-1, and OP$^-$. None of these strains is reported to meet the limitations of "an lgtB$^-$ neisserial strain with an L3 LOS immunotype," nor does the Examiner point to any particular disclosure of Quakyi that indicates that any of strains M986, M986-NCV-1 or OP$^-$ meets these limitations. Accordingly, Quakyi does not destroy the novelty or otherwise disclose the special technical feature of the instantly claimed invention.

Conclusion

Applicants elect Group I b) without traverse, and provisionally elect the downregulated capsular polysaccharide gene siaD with traverse for the reasons explained above. Applicants respectfully request the opportunity to discuss the Restriction Requirement with the Examiner before the action is made final. Applicants reserve the right to prosecute the subject matter in the non-elected claims, originally filed claims, or any other claims supported by the specification in one or more continuing patent applications.

Respectfully submitted,

Gwynedd Warren
Attorney for Applicants
Registration No. 42,500

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-7241
Facsimile (610) 270-5090